APR 1 0 2000

K000979

Attachment 4

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is:

1. Date of summary: March 17, 2000

2. Submitted by: Redwood Biotech Inc. 3573 Westwind Blvd. Santa Rosa, CA 95403 TEL 707-577-7959 FAX 707-577-0365
Contact: Robert Mount

3. Device Name: Redi-Screen

4. Device Classification: Class II, Panel 91 Toxicology

5. Device description: The Redi-Screen is an immunochromatographic based one step *in vitro* test.

6. Intended Use: The Redi-Screen is designed for the qualitative determination of five (5) DOA and their metabolites in human urine specimens. The five DOA include THC, PCP, Opiates, Cocaine and Methamphetamine. The presence of these drugs and their cross-reacting metabolites in human urine can be detected above the following cut off levels:

THC	50ng/mL
PCP	25ng/mL
Opiates	300ng/mL
Cocaine	300ng/mL
Methamphetamine	1,000ng/mL

The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

This test is for use in clinical laboratories by health care and forensic professionals only.

7. Substantial Equivalence: The Redi-Screen was found substantially equivalent to the five single tests for the individual DOA, i.e., the Redi-THC, Redi-PCP, Redi-Cocaine, Redi-Opiates and Redi-Methamphetamine. All products are immunoassays and use specific antibodies to detect various drug compounds. Both predicate and modified tests are preliminary screens for human urine and require confirmation with alternate methods such as GC/MS. The sensitivity for the Redi Screen is equivalent to the single tests.

Conclusion:
The Redi-Screen is substantially equivalent to the individual Redi-Test THC, Opiates PCP, Cocaine and Methamphetamine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2000

Redwood Biotech Inc.
c/o Ms. Janis Freestone
Charlton Associates
1206 Sesame Drive
Sunnyvale, California 94087

Re: K000979
Trade Name: Redi-Screen
Regulatory Class: II
Product Code: LAF, LDJ, LCM, DJG, DIO
Dated: March 23, 2000
Received: March 27, 2000

Dear Ms. Freestone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2

510k Number: K000979

Device Name:
Redi-Screen

Indications for Use:

The Redi-Screen is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of THC, Phencyclidine, Opiates, Cocaine and Methamphetamine at the following cut off concentrations;

THC	50ng/mL
PCP	25ng/mL
Opiates	300ng/mL
Cocaine	300ng/mL
Methamphetamine	1,000ng/mL

The test is qualitative and provides only a preliminary analytical result, which must be confirmed by an alternate methodology preferably, GC/MS.

(Division Sign-Off)
Division of Clinical Lab...
510(k) Number: K000979

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the counter use_____
(Per 21 CFR 801.109)